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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KAROL, JODY LYNN	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,605	WAKAMATSU ET AL.	
	Examiner	Art Unit	
	Jody L. Karol	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/11/2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,7-10,12,15,17,18 and 21-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5, 7-10, 12, 15, 17-18, and 21-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/11/2009 has been entered.

Claims 1, 12, and 18 have been amended. Claims 2-4, 6, 11, 13-14, 16, 19-20 have been cancelled. Claims 21-30 are newly added. Thus, claims 1, 5, 7-10, 12, 15, 17-18, and 21-30 are pending and currently under consideration.

Response to Arguments

1. Applicant's arguments filed 2/11/2009 have been fully considered but they are not persuasive.

Applicant alleges that the selection of ascorbic acid requires improper hindsight based on the teaching of the instant specification, and that Wakamatsu et al. do not teach the combination of AMP with ascorbic acid or derivatives thereof.

In response it is respectfully submitted that it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). While it is noted that ascorbic acid is one of several electrolytes listed in the teachings of Wakamatsu et al., ascorbic 2-glucoside is specifically taught by Castiel et al. to have an anti-aging action. Adenosine monophosphate is also specifically taught by Wakamatsu et al. to have an anti-aging action. Thus, the combination of adenosine monophosphate with ascorbic 2-glucoside is not based on hindsight reasoning, but on the basis that both components have an anti-aging action. It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose *In re Kerkhoven*, 626 F.2d 846, 205, U.S.P.Q. 1069 (C.C.P.A. 1980).

The Applicant further alleges that Castiel et al. is silent about the method for improving the anti-aging effect of vitamin C derivatives and that the stability enhancement of vitamin C derivatives is irrelevant to the improvement of the anti-aging effect. In response it is respectfully submitted that the improvement of the anti-aging effect of ascorbyl 2-glucoside comes from combining it with adenosine monophosphate. As stated above, both ascorbyl 2-glucoside and adenosine monophosphate are taught by Wakamatsu et al. and Castiel et al. to have anti-aging action. The combination of ascorbyl 2-glucoside and adenosine monophosphate used for the same purpose of anti-aging action is expected to have up to an additive effect. Furthermore, the enhanced anti-aging action of ascorbyl 2-glucoside compared to ascorbic acid is a feature that is not claimed.

The Applicant also alleges that Castiel et al. do not teach ascorbyl 2-glucoside is depigmenting agent. The Examiner respectfully disagrees. Castiel et al. teach ascorbyl 2-glucoside is useful as a depigmenting agent (see pages 1-2, section [0021]).

The Applicant alleges that the synergism between ascorbic 2-glucoside and a purine related substance as demonstrated by the specification is unexpected because the components act by different mechanisms, and neither of the mechanisms have to do with skin pigmentation. In response it is respectfully submitted that both ascorbic 2-glucoside and adenosine monophosphate are taught by Wakamatsu et al. and Castiel et al. to have skin anti-aging action, and skin aging is characterized by uneven and/or hyperpigmentation of the skin as taught by Quan et al. (US 6180,133 B1).

Further, it is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

In the instant case, the "evidence" of alleged synergism is not commensurate with the breadth of the claims. Only one specific comparative example is provided on pages 22-24 of the instant specification, and in Figure 1, as evidence for combining ascorbic-2-glucoside and AMP in 20% isopropanol to synergistically potentiate the

effect of alleviating pigmentation, which is not necessarily attributed to an anti-aging effects claimed in the instant claims 15 and 17-18. Furthermore, the Example only tests the effect of alleviating pigmentation wherein 2% of each of the components is present. One example with a specific amount of each component does not provide sufficient evidence that the remaining compositions possible under the claim scope would exhibit the same of similar results. For example, the Example does not provide sufficient evidence that a composition comprising 10% by weight AMP and 10% by weight ascorbyl 2-glucoside would have a similar synergistic effect in alleviating skin pigmentation. Therefore, no clear and convincing unexpected benefit is seen to be present herein.

Thus, for these reasons, Applicant's arguments are found unpersuasive. Said rejection is maintained.

REJECTIONS

2. The following rejections and/or objections are either maintained from the previous Office Action dated 8/11/2008 or newly applied. They constitute the complete set of rejections and/or objections presently being applied in the instant application. The newly applied rejections are necessitated by the newly added claims 21-30.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 5, 7-10, and 21-26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-6 of copending Application No. 11/722965.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims sets are directed to composition comprising an adenosine monophosphate and an ascorbic acid derivative, such as ascorbic-2-glucoside. There are additional components present in the compositions of the copending claims. However, the term "comprising" is interpreted as broad and open-ended, and other components not mentioned may be present in the compositions of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1, 5, 7-10, 12, 15, 17-18, and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wakamatsu et al. (WO 2002/41853) in view of Castiel et al. (US 2002/0042380 A1). US 6,946,436 B2 is used as the English equivalent of Wakamatsu et al. (WO 2002/41853).

Claims 1, 5, 7-10, and 21-26 are directed to compositing comprising ascorbic acid 2-glucoside and an adenosine monophosphate (AMP). Claim 5 specifies that the AMP is adenosine 5'-monophosphate or salt thereof. Claims 7-9 further limit the amount of the components. The instant claims 12, 15, and 17 are directed to methods of potentiating an anti-aging action of a composition comprising ascorbic acid 2-glucoside comprising incorporating an adenosine monophosphate or salt thereof into the composition. Claim 18 is directed to method for retarding skin aging comprising applying to the skin ascorbic acid 2-glucoside and adenosine monophosphate or salt thereof. Wakamatsu et al. teach an O/W emulsion composition comprising an electrolyte, where the preferred electrolytes are adenosine monophosphate, cyclic adenosine monophosphate, salts thereof, ascorbic acid, and derivatives thereof (see column 7, lines 9-36 and claims 3-4). The adenylic acid derivatives (i.e. adenosine monophosphate) are known to exhibit moisturizing and anti-aging effects when applied to the skin (see column 7, lines 45-54 and column 16, lines 1-15). The placing of the

phosphate group of adenosine monophosphate (AMP) is not specified, however, a phosphate group can only attach on an adenosine molecule where there is a hydroxyl group. Hydroxyl groups are present on adenosine at the 2', 3' and 5' positions, so the AMP must be adenosine 2'-monophosphate, adenosine 3'-monophosphate, adenosine 5'-monophosphate, or mixtures thereof. Wakamatsu et al. further teach that the electrolytes can be used alone or in combination of two or more species (see column 7, lines 39-40) and the amount of electrolytes contained in the composition is not limited, but is at least 0.1% by weight, and preferably 0.5 to 7% by weight as claimed in the instant claims 7-9 and 23-25 (see column 7, line 66 to column 8, line 5 and claims 12-14). Wakamatsu et al. teaches specific examples where adenosine monophosphate disodium is present in the composition in 1.5%, 3.0% and 6.0% by weight (see Table 1, examples 1-4) and where sodium L-ascorbic acid phosphate ester (L-ascorbyl phosphate salt) is present in the composition in 2.0 and 3.0% by weight (see Table 1, examples 5-6).

Wakamatsu et al. do not teach compositions comprising ascorbic 2-glucoside, or that ascorbic 2-glucoside is an acceptable ascorbic acid derivative. Wakamatsu et al. do not explicitly teach adenosine 5'-monophosphate as claimed in the instant claims 5 and 22. Wakamatsu et al. do not teach the method of potentiating an anti-aging effect or an skin pigmentation alleviating effect by incorporating AMP into a composition comprising ascorbic 2-glucoside as claimed in the instant claims 12, 15, 17, and 27-29. Wakamatsu et al. do not teach the method applying the herein claimed composition to

the skin to prevent aging or alleviate skin pigmentation as claimed in the instant claims 18 and 30.

Castiel et al. teach Vitamin C derivatives that are more stable than ascorbic acid itself and which combat or prevent intrinsic aging of the skin (see abstract). One of the preferred ascorbic acid derivatives is a 2-O-α-D-glucopyranosyl of ascorbic acid, also known as ascorbic acid 2-glucoside (see page 2, sections 32, 35, and 41). Ascorbic 2-glucoside is known to be useful as a depigmenting agent (see pages 1-2, section [0021]). Castiel et al. further teaches the compositions contain 0.001 to 10% by weight of ascorbic acid derivatives (see page 2, section 42), and gives an example of a composition with ascorbic acid 2-glucoside present in 0.1% by weight of the composition (see page 4, section 77).

It would have been obvious to one having ordinary skill in the art at the time of the invention to combine adenosine monophosphate with another electrolyte, such as an ascorbic acid derivative, as taught by Wakamatsu et al., wherein the ascorbic acid derivative is ascorbic acid 2-glucoside as taught Castiel et al. One of ordinary skill in the art would have been motivated to do so in order to formulate a composition with anti-aging action, since adenosine monophosphate derivatives and ascorbic acid derivatives are both used individually in the art for the same purpose, namely to keep skin from aging. It is obvious to one of ordinary skill in the art to combine components taught individually in the art as having the same purpose to form a new composition for the very same purpose. *In re Kerkhoven*, 626 F.2d 846, 205, U.S.P.Q. 1069 (C.C.P.A. 1980). In regards to claims 12, 15, and 17, the combination of ascorbyl 2-glucoside and

adenosine monophosphate used for the same purpose of anti-aging action, is expected to have up to an additive effect. Thus the anti-aging action of ascorbyl 2-glucoside is considered to be enhanced by combination with adenosine monophosphate.

Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention to apply the composition obvious over Wakamatsu et al. in view of Castiel et al. to the skin for its intended use to retard aging. One of ordinary skill in the art would have been motivated to retard skin aging by applying the composition Wakamatsu et al. in view of Castiel et al. to the skin with a reasonable expectation of success because it is obvious to use a composition for its intended used.

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

7. Claims 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wakamatsu et al. (WO 2002/41853) in view of Castiel et al. (US 2002/0042380 A1) as applied to claims 1, 5, 7-10, 12, 15, 17-18, and 21-26 above and in further view of Quan et al. (US 6,180,133 B1).

Claims 27-29 are directed to methods of potentiating a skin pigmentation alleviating action of a composition comprising ascorbic acid 2-glucoside comprising incorporating an adenosine monophosphate or salt thereof into the composition. Claim 30 is directed to method for alleviating skin pigmentation comprising applying to pigmented skin ascorbic acid 2-glucoside and adenosine monophosphate or salt thereof.

Wakamatsu et al. in view of Castiel et al. is described *supra* as applied to claims 1, 5, 7-10, 12, 15, 17-18, and 21-26.

Wakamatsu et al. and Castiel et al. do not teach potentiating a skin pigmentation alleviating action of a composition comprising ascorbic acid 2-glucoside comprising incorporating an adenosine monophosphate or salt thereof into the composition or alleviating skin pigmentation comprising applying to pigmented skin ascorbic acid 2-glucoside and adenosine monophosphate or salt thereof.

Quan et al. teach that aging of the skin is caused by a combination of extrinsic and intrinsic factors, and may be characterized by wrinkling of the skin, uneven or hyperpigmentation, loss of distensibility and uneven texture *inter alia* (see column 2, lines 3-47).

It would have been obvious to one of ordinary skill in the art at the time of the invention, to potentiate a skin pigmentation alleviating effect by adding adenosine monophosphate to ascorbic 2-glucoside as obvious over Wakamatsu et al. in view of Castiel et al. because Quan et al. teach uneven and/or hyperpigmentation of the skin are signs of skin aging. One of ordinary skill in the art would have been motivated to add by adding adenosine monophosphate to ascorbic 2-glucoside to form a composition for treating aging and skin pigmentation. One of ordinary skill in the art would have had a reasonable expectation of success of adding adenosine monophosphate to ascorbic 2-glucoside to potentiate a skin pigmentation alleviating effect because both adenosine monophosphate and ascorbic 2-glucoside are taught by Wakamatsu et al. and Castiel et al. to have anti-aging action, and skin aging is characterized by uneven and/or

hyperpigmentation of the skin as taught by Quan et al. Thus it can be reasonably expected that in enhancing the anti-aging action of ascorbic 2-glucoside by adding adenosine monophosphate, the skin pigmentation alleviating effect is also enhanced.

Furthermore, in regards to claim 30, it would have been obvious to one of ordinary skill in the art to apply the composition comprising ascorbic 2-glucoside and adenosine monophosphate as obvious over Wakamatsu et al. in view of Castiel et al. to pigmented skin to alleviate skin pigmentation. One of ordinary skill in the art would have been motivated to apply the composition comprising ascorbic 2-glucoside and adenosine monophosphate as obvious over Wakamatsu et al. in view of Castiel et al. to pigmented skin to treat pigmented skin associated with aging. One of ordinary skill in the art would have had a reasonable expectation of success in alleviating skin pigmentation by applying the composition comprising ascorbic 2-glucoside and adenosine monophosphate as obvious over Wakamatsu et al. in view of Castiel et al. to pigmented skin because ascorbic 2-glucoside and adenosine monophosphate are taught by Wakamatsu et al. and Castiel et al. to have anti-aging action, and skin aging is characterized by uneven and/or hyperpigmentation of the skin as taught by Quan et al.

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claims are allowed.

Correspondence

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571)270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Jody L. Karol/

Examiner, Art Unit 1617

/JENNIFER M KIM/
Primary Examiner, Art Unit 1617